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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,909	08/22/2001	Richard A. Fishel	9855-6U3	9339

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EXAMINER

ZITOMER, STEPHANIE W

ART UNIT PAPER NUMBER

1634

DATE MAILED: 07/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/934,909

Applicant(s)

FISHEL ET AL.

Examiner

Stephanie Zitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32,33,35,37,39,40,42 and 44-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 32,33,35,37,39,40,42 and 44-54 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## RESTRICTION

### Restriction

The restriction applied in parent application 09/143,571 is applied herein to the claims remaining after prosecution of elected Group I claims in '571.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - II. Claims 35, 37 and 39, drawn to a method of fractionating DNAs and kit therefor, classified in class 536, subclass 25.4;
  - III. Claim 40, drawn to a method of amplifying DNA, classified in class 435, subclass 91.2;
  - IV. Claims 42, 51 and 53, drawn to a protein composition, classified in class 530, subclass 350;
  - V. Claim 44, drawn to a nonhuman animal, classified in class 800, subclass 2;
  - VI. Claim 45, drawn to a method of animal breeding, classified in class 800, subclass DIG 4;
  - VII. Claims 46, 47, 49 and 50, drawn to a method of *in vivo* testing, classified in class 424, subclass 9.1;
  - VIII. Claim 48, drawn to a cell line, classified in class 435, subclass 325;
  - IX. Claim 52, drawn to a method of treating with protein, classified in class 514, subclass 2;
  - X. Claim 54, drawn to a nucleic acid composition, classified in class 536, subclass 23.1.
2. Inventions I-III, VI, VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, MEP. § 808.01). In the instant case the different inventions have different modes of operations, *viz.*, contacting DNA with a protein; detecting a protein-DNA complex; separating DNA molecules; amplifying DNA; breeding animals; testing *in vivo*; treating a human, respectively. Due to their different modes of operation the invention methods have different functions and/or effects, *viz.*, modification of DNA; identified protein-DNA complex;

isolated DNAs; amplified DNA products; animal with desired phenotype; identification of protein-inhibiting compound; human with inhibited protein function, respectively.

3. Inventions IV, V, VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MEP. § 806.04, MEP. § 808.01). In the instant case the different inventions are different chemical compounds and compositions, *v/z.*, proteins composed of amino acids; organs, tissues and bone composed of other chemical compounds in addition to proteins; nucleic acids, ribosomes, lipids and other chemical compounds in addition to proteins; nucleic acids composed of nucleotides, respectively.-

4. Inventions IV and I-III, VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MEP. § 806.05(h)). In the instant case the product protein can be used as a molecular weight marker in a chromatography process..

5. Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MEP. § 806.05(h)). In the instant case the product animal can be used as a source of protein in an extraction process.

6. Inventions V and VIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MEP. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination has other cells which function better than the subcombination cell. The subcombination has separate utility such as for cloning.

7. Inventions VI and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MEP. § 806.05(f)). In the instant case the product as claimed can be made by a transgenic process.
8. Inventions X and I-III, VI, VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MEP. § 806.04, MEP. § 808.01). In the instant case the different inventions are not used together as Invention XI is a nucleic acid and the methods of the other inventions use proteins or an animal.
9. Inventions VIII and 1-III, VI, VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MEP. § 806.04, MEP. § 808.01). In the instant case the different inventions are not used together as Invention VIII is a cell and the methods of the other inventions use proteins or an animal.
10. Inventions V and 1-III, VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MEP. § 806.04, MEP. § 808.01). In the instant case the different inventions are not used together as Invention VI is an animal and the methods of the other inventions use proteins.
11. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.
12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CAR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

**Contact information**

**16.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*S. Zitomer*  
Stephanie Zitomer, Ph.D.  
July 8, 2002

SIGNATURE OF EXAMINER  
PRIMA FIDELITY